

STN	Zariadenia s krátkym dosahom (SRD) Bezdrôtové lekárske zariadenia veľmi nízkeho výkonu (ULP) pre kapsulovú endoskopiú pracujúce v pásme od 430 MHz do 440 MHz Harmonizovaná norma pre prístup k rádiovému spektru	STN EN 303 520 V1.1.1 87 3520
------------	--	---

Short Range Devices (SRD); Ultra Low Power (ULP) wireless medical capsule endoscopy devices operating in the band 430 MHz to 440 MHz; Harmonised Standard for access to radio spectrum

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/19

Obsahuje: EN 303 520 V1.1.1:2018

128969

ETSI EN 303 520 V1.1.1 (2018-07)



HARMONISED EUROPEAN STANDARD

**Short Range Devices (SRD);
Ultra Low Power (ULP) wireless medical capsule endoscopy
devices operating in the band 430 MHz to 440 MHz;
Harmonised Standard for access to radio spectrum**

Reference

DEN/ERM-TG30-315

Keywords

harmonised standard

ETSI

650 Route des Lucioles
F-06921 Sophia Antipolis Cedex - FRANCE

Tel.: +33 4 92 94 42 00 Fax: +33 4 93 65 47 16

Siret N° 348 623 562 00017 - NAF 742 C
Association à but non lucratif enregistrée à la
Sous-Préfecture de Grasse (06) N° 7803/88

Important notice

The present document can be downloaded from:

<http://www.etsi.org/standards-search>

The present document may be made available in electronic versions and/or in print. The content of any electronic and/or print versions of the present document shall not be modified without the prior written authorization of ETSI. In case of any existing or perceived difference in contents between such versions and/or in print, the only prevailing document is the print of the Portable Document Format (PDF) version kept on a specific network drive within ETSI Secretariat.

Users of the present document should be aware that the document may be subject to revision or change of status.

Information on the current status of this and other ETSI documents is available at

<https://portal.etsi.org/TB/ETSIDeliverableStatus.aspx>

If you find errors in the present document, please send your comment to one of the following services:

<https://portal.etsi.org/People/CommiteeSupportStaff.aspx>

Copyright Notification

No part may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm except as authorized by written permission of ETSI.

The content of the PDF version shall not be modified without the written authorization of ETSI.

The copyright and the foregoing restriction extend to reproduction in all media.

© ETSI 2018.

All rights reserved.

DECT™, **PLUGTESTS™**, **UMTS™** and the ETSI logo are trademarks of ETSI registered for the benefit of its Members.

3GPP™ and **LTE™** are trademarks of ETSI registered for the benefit of its Members and of the 3GPP Organizational Partners.

oneM2M logo is protected for the benefit of its Members.

GSM® and the GSM logo are trademarks registered and owned by the GSM Association.

Contents

Intellectual Property Rights	5
Foreword.....	5
Modal verbs terminology.....	5
Introduction	6
1 Scope	7
2 References	7
2.1 Normative references	7
2.2 Informative references.....	7
3 Definitions, symbols and abbreviations	8
3.1 Definitions	8
3.2 Symbols.....	8
3.3 Abbreviations	8
4 Technical requirements specifications	9
4.1 Environmental profile.....	9
4.2 Conformance requirements	9
4.2.1 Transmitter requirements	9
4.2.1.1 Effective radiated power	9
4.2.1.1.1 Definition.....	9
4.2.1.1.2 Limit	9
4.2.1.1.3 Conformance	9
4.2.1.2 Transmitter emissions mask	9
4.2.1.2.1 Definition.....	9
4.2.1.2.2 Limits	9
4.2.1.2.3 Conformance	10
4.2.2 Receiver requirements	10
4.2.2.1 Unwanted Emissions in the Spurious Domain	10
4.2.2.1.1 Definition.....	10
4.2.2.1.2 Limit	10
4.2.2.1.3 Conformance	10
4.2.2.2 Receiver blocking	10
4.2.2.2.1 Definition.....	10
4.2.2.2.2 Limits	11
4.2.2.2.3 Conformance	11
4.2.2.3 Receiver sensitivity	11
4.2.2.3.1 Definition.....	11
4.2.2.3.2 Limit	11
4.2.2.3.3 Conformance	11
4.2.2.4 Adjacent signal selectivity	11
4.2.2.4.1 Definition.....	11
4.2.2.4.2 Limit	11
4.2.2.4.3 Conformance	11
5 Testing for compliance with technical requirements.....	12
5.1 Presentation of equipment for testing purposes.....	12
5.1.0 General provisions	12
5.1.1 Choice of equipment model for testing.....	12
5.1.2 Human torso simulator.....	12
5.1.3 Testing in external laboratory	12
5.2 Test conditions	12
5.2.1 Test power source	12
5.2.2 Temperature and humidity.....	13
5.2.3 Test signals and test modulation.....	13
5.2.4 Antennas	13
5.2.5 Test fixture for CCam	13

5.2.6	Test site and general arrangements for radiated measurements	13
5.2.7	Measuring receiver	13
5.3	Interpretation of the measurement results	13
5.4	Methods of measurement	14
5.4.1	Methods of measurement for transmitters	14
5.4.1.0	General provisions	14
5.4.1.1	Effective radiated power	14
5.4.1.2	TX emissions mask compliance measurement	15
5.4.2	Methods of measurement for receivers	16
5.4.2.1	Receiver's unwanted emissions in the spurious domain	16
5.4.2.2	Receiver blocking	16
5.4.2.2.0	Types of measurement	16
5.4.2.2.1	Radiated measurement	16
5.4.2.2.2	Conducted measurement	17
5.4.2.2.3	Measurement procedure	17
5.4.2.3	Receiver sensitivity	18
5.4.2.3.0	Types of measurement	18
5.4.2.3.1	Radiated measurement	18
5.4.2.3.2	Conducted measurement	18
5.4.2.3.3	Measurement procedure	18
5.4.2.4	Adjacent signal selectivity	19
Annex A (informative):	Relationship between the present document and the essential requirements of Directive 2014/53/EU	20
Annex B (normative):	Human torso simulator	21
B.1	General provisions	21
B.2	Human torso simulator for CCam radiated measurements	21
Annex C (normative):	Test site and antennas for radiated measurements	23
C.1	Test site description	23
C.2	Antennas	24
C.2.1	Measurement antenna	24
C.2.2	Substitution antenna	24
C.3	Guidance on the use of radiation test site	24
C.3.0	General	24
C.3.1	Site preparation	24
C.4	Radiated measurement methods for receivers	25
Annex D (informative):	Change history	26
History	27

Intellectual Property Rights

Essential patents

IPRs essential or potentially essential to normative deliverables may have been declared to ETSI. The information pertaining to these essential IPRs, if any, is publicly available for **ETSI members and non-members**, and can be found in ETSI SR 000 314: "*Intellectual Property Rights (IPRs); Essential, or potentially Essential, IPRs notified to ETSI in respect of ETSI standards*", which is available from the ETSI Secretariat. Latest updates are available on the ETSI Web server (<https://ipr.etsi.org/>).

Pursuant to the ETSI IPR Policy, no investigation, including IPR searches, has been carried out by ETSI. No guarantee can be given as to the existence of other IPRs not referenced in ETSI SR 000 314 (or the updates on the ETSI Web server) which are, or may be, or may become, essential to the present document.

Trademarks

The present document may include trademarks and/or tradenames which are asserted and/or registered by their owners. ETSI claims no ownership of these except for any which are indicated as being the property of ETSI, and conveys no right to use or reproduce any trademark and/or tradename. Mention of those trademarks in the present document does not constitute an endorsement by ETSI of products, services or organizations associated with those trademarks.

Foreword

This Harmonised European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

The present document has been prepared under the Commission's standardisation request C(2015) 5376 final [i.1] to provide one voluntary means of conforming to the essential requirements of Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC [i.2].

Once the present document is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of the present document given in Table A.1 confers, within the limits of the scope of the present document, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

National transposition dates	
Date of adoption of this EN:	17 July 2018
Date of latest announcement of this EN (doa):	31 October 2018
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	30 April 2019
Date of withdrawal of any conflicting National Standard (dow):	30 April 2020

Modal verbs terminology

In the present document "**shall**", "**shall not**", "**should**", "**should not**", "**may**", "**need not**", "**will**", "**will not**", "**can**" and "**cannot**" are to be interpreted as described in clause 3.2 of the [ETSI Drafting Rules](#) (Verbal forms for the expression of provisions).

"**must**" and "**must not**" are **NOT** allowed in ETSI deliverables except when used in direct citation.

Introduction

The present document is aiming to cover radio and telecommunications terminal equipment within the scope of the EU's Radio Equipment Directive (RED) [i.2].

The present document specifies conformance requirements for the Ultra Low Power Wireless Medical Capsule Endoscopy SRD application, which includes Capsule Camera (CCam) acting as transmitter and associated Data Recorder (DR) receiver devices, as meant by ETSI TR 103 451 [i.3]. The CCam is designed to wirelessly transmit recorded images from inside patient's gastrointestinal tract to the DR receiver, utilizing a single wideband radio channel occupying the entire designated band 430 MHz to 440 MHz. It is intended that this band will be harmonised for European-wide usage by Ultra Low Power Wireless Medical Endoscopy application through relevant CEPT and EU normative documents in the field of SRD spectrum regulation, such as CEPT/ERC/REC 70-03 [i.4].

CCam transmitters will utilize miniature integral antenna encapsulated within its pill-shaped enclosure. The intended use of the CCam transmitter is inside the human body.

DR receivers will use either integral antenna or dedicated external antenna implemented in the form of skin patch or belt. Such dedicated external antenna would ensure optimal reception of weak radio signals by keeping antenna in direct proximity to the patient's body in the area closest to internal passage of CCam.

These devices would offer opportunity of performing medical endoscopy-type examination of the entire human gastrointestinal tract including the small intestine and colon. Thanks to simple application with minimized risks and side effects, while providing the unique ability to visualize the complete gastrointestinal tract, its use would be highly beneficial and attractive to patients and doctors.

The present document is structured as follows:

- Clauses 1 through 3 provide a general description of the types of equipment covered by the present document and the definitions of terms, symbols and abbreviations used.
- Clause 4 specifies the requirements and limits applicable to CCam transmitter and DR receiver.
- Clauses 5.1 and 5.2 specify the test and general conditions for testing of the equipment.
- Clause 5.3 specifies the methods of measurement for the parameters specified in clause 4.
- Annex A (informative) provides an overview of the relationship between the present document and the essential requirements of the RED [i.2].
- Annex B (normative) describes a human torso simulator test fixture to be used for radiated measurements.
- Annex C (normative) describes the Full Anechoic Room test site configuration for radiated measurements.

1 Scope

The present document specifies technical characteristics and methods of measurements for Ultra Low Power Wireless Medical Capsule Endoscopy application (CCam transmitters and associated DR receivers) operating in the designated frequency band 430 MHz to 440 MHz, as meant by ETSI TR 103 451 [i.3].

A possible return (downlink) RF transmission channel from DR to CCam for command and control signalling, if and when implemented, will be outside the scope of the present document.

NOTE: The relationship between the present document and essential requirements of article 3.2 of Directive 2014/53/EU [i.2] is given in Annex A.

2 References

2.1 Normative references

References are specific, identified by date of publication and/or edition number or version number. Only the cited version applies.

Referenced documents which are not found to be publicly available in the expected location might be found at <https://docbox.etsi.org/Reference/>.

NOTE: While any hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long term validity.

The following referenced documents are necessary for the application of the present document.

Not applicable.

2.2 Informative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

NOTE: While any hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long term validity.

The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

- [i.1] Commission Implementing Decision C(2015) 5376 final of 4.8.2015 on a standardisation request to the European Committee for Electrotechnical Standardisation and to the European Telecommunications Standards Institute as regards radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council.
- [i.2] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (RED).
- [i.3] ETSI TR 103 451: "System Reference document (SRdoc); Short Range Devices (SRD); Technical characteristics for UHF wideband Ultra Low Power Wireless Medical Capsule Endoscopy".
- [i.4] CEPT/ERC/REC 70-03: "Relating to the use of Short Range Devices (SRD)".
- [i.5] Body Tissue Dielectric Parameters. Reference Calculation Tool provided by the Federal Communications Commission.

NOTE: Available online at: <https://www.fcc.gov/general/body-tissue-dielectric-parameters>.

- [i.6] Hartsgrove, G., Kraszewski, A. & Surowiec, A. (1987): "Simulated biological materials for electromagnetic radiation absorption studies". *Bioelectromagnetics*, 8(1), 29-36.

koniec náhľadu – text ďalej pokračuje v platenej verzii STN